MAR 1 9 2001

# Special 510(k) Summary
# Accu-Chek Inform Meter – 510(k) #k003846

**Introduction**

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**1) Submitter name, address, contact**

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000
Contact Person: Mike Flis
Date Prepared: February 16, 2001

**2) Device name**

Proprietary name: Accu-Chek™ Inform® Meter
Common name: whole blood glucose test system
Classification name: Glucose dehydrogenase, glucose

**3) Predicate device**

We claim substantial equivalence to the Roche Diagnostics Accu-Chek Advantage Meter.

**4) Device Description**

The Accu-Chek Inform system is addition to the Accu-Chek brand of blood glucose monitors that incorporates the fundamental scientific technology currently found in the Accu-Chek Advantage Meter.

The Accu-Chek Inform Meter is a modification to the Accu-Chek Advantage Meter that involves integrating the AccuData GTS unit's data gathering features into the meter. The Accu-Chek Inform Meter may be used in conjunction with the same test strips indicated for use with the Accu-Chek Advantage Meter, and the test principle described on the following page is not affected by the design modifications.

This modification can be accomplished due in part to the availability of palm-powered computers (PDA). The PDA module enabled our designers to integrate the AccuData GTS unit's data gathering features into the meter itself. The Accu-Chek Inform Meter was designed to be convenient and easy to use.

**5) Intended use**

The Accu-Chek Inform Meter is designed to quantitatively measure the concentration of glucose in whole blood samples. The device is indicated for use by health care professionals.

*Continued on next page*

# Summary of Safety & Effectiveness, Continued

**6) Comparison to predicate device**

The Roche Diagnostics Accu-Chek Inform Meter is substantially equivalent to the Accu-Chek Advantage Meter, as the following table shows.

| | **Accu-Chek Advantage Meter (predicate device)** | **Accu-Chek Inform Meter** |
|---|---|---|
| Intended use | The meter is designed to quantitatively measure the concentration of glucose in a whole blood sample. | No change |
| Indications for use | The device is indicated for professional use and over-the-counter sale. | Professional use only |
| Fundamental scientific technology | The measurement is accomplished by applying a controlled voltage between two identical electrodes embedded within the test strip, which causes the reduced mediator formed during the glucose dehydrogenase reaction to be reconverted to an oxidized mediator. This generates a small current that is measured by the meter. The meter's software converts this electrical currency signal into a blood glucose value. The manufacturer establishes the system's correlation to a comparative laboratory method; each test strip vial is packaged with a calibration code key that the user insets into the meter to ensure an appropriate calibration. | No change |
| System components | Test strips – Accu-Chek Advantage or Accu-Chek Comfort Curve<br>Liquid controls – Accu-Chek Advantage or Accu-Chek Comfort Curve (controls are linked to the test strip model used) | No change |
| Analytical performance claims | Derived from testing with the two test strips listed above. Claims are stated in test strip package inserts. Meter model does not significantly affect analytical performance claims. | No change |
| Performance comparisons | Derived from testing with the two test strips listed above. Claims are stated in test strip package inserts. Meter model does not significantly affect method comparison results. | No change |
| Data management | Home use – blood glucose and liquid control testing results<br>Health care provider (w/AccuData GTS) – blood glucose, liquid control, linearity, and proficiency testing results and operator and patient identification | No change |
| Technical Service | Accu-Chek Customer Care Center available to respond to customer questions via a toll-free telephone service around-the-clock, every day of the year. | No change |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: K003846
Trade Name: Accu-Chek™ Inform® Meter
Regulatory Class: II
Product Code: CGA
Dated: February 16, 2001
Received: February 20, 2001

Dear Mr. Flis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use Statement

## Special 510(k) Number (if known): K003846
## Device Name: Accu-Chek™ Inform® Meter

Indications for Use:

The Accu-Chek Inform Meter is designed to quantitatively measure the concentration of glucose in whole blood samples. The device is indicated for use by health care professionals.

The Accu-Chek Inform Meter is an addition to the Accu-Chek brand of blood glucose instruments that incorporates the fundamental scientific technology currently found in the Accu-Chek Advantage Meter and Accu-Chek Complete Meter. The Accu-Chek Inform Meter is designed for use in conjunction with either the Accu-Chek Advantage or Accu-Chek Comfort Curve test strips.

The Accu-Chek Inform Meter is equipped with sophisticated data management and communication features that enable the user to record blood glucose and quality control test data and other information relevant to proper diabetes management.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003846

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)